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Title: Anti-interleukin-5 in severe asthma: Blood eosinophilia predicts lung function improvement

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Body: In recent trials in patients with severe eosinophilic asthma a clinical benefit of treatment with anti-IL-5 antibodies was only demonstrated in terms of exacerbations. Aim of the present analyses was to identify patient characteristics associated with a treatment response beyond exacerbations. 45 patients (27 [female], mean±SEM: age 51.3±1.3 yrs., FEV1 1.7±0.1 L / 57.2±2.7 % pred., FeNO 54.9±7.8 ppb, blood eosinophils 440/µl (median, range 10-2100/µl) were treated with an anti-IL-5-antibody for up to 12 months as part of blinded, randomized clinical trials (36 mepolizumab or reslizumab, 9 placebo). There was no FEV1 benefit after 1, 4 or 12 months in patients treated with placebo (median change 1.2%, -5.5% and -2.9%). In patients treated with anti-IL-5 FEV1 increased significantly by 17.9% (265 ml) after 1 month ($p<0.001$), by 17.3% (240 ml) after 4 months ($p=0.002$) and by 21.1% (295 ml) after 12 months ($p=0.003$). FEV1 response to anti-IL-5 was fast with maximum effects already seen after the first month. In patients with ≥600 eosinophils/µl FEV1 increased by 30.1% after 1 month and by 27.8% after 12 months, compared with 15.6% and 10.7% in patients with ≤300 eosinophils/µl ($p=0.065$, 1 month; $p=0.277$, 12 months). In contrast, sputum eosinophilia (≥ 2%) or FeNO did not predict FEV1 response (change in FEV1 after 1 month: sputum eosinophils <2% vs. ≥2% 17.2 vs. 11.0%, FeNO <50 ppb vs. ≥50 ppb 17.4 vs. 19.6%). In conclusion, the clinical benefits of anti-IL-5 in patients with eosinophilic asthma may well reach beyond exacerbations. Anti-IL-5 treatment seems to be most effective in asthma patients characterized by blood eosinophilia.